

Checklist for Setting up an Account with the FDA Electronic Submissions Gateway (ESG)

For policy questions and to request a WebTrader account, contact esgprep@fda.hhs.gov.

For assistance with the registration or testing process, contact esgreg@gnsi.com.

For Electronic Drug Registration and Listing checklist, please see:

<http://www.fda.gov/ForIndustry/ElectronicSubmissionsGateway/ucm177328.htm>

For Center for Tobacco Products Registration checklist, please see:

<http://www.fda.gov/ForIndustry/ElectronicSubmissionsGateway/ucm188949.htm>

Before you Start	
<input type="checkbox"/>	1. Send an email to esgprep@fda.hhs.gov requesting a WebTrader test account. Provide the following information: Company name, your name, phone number and submission method (WebTrader).
<input type="checkbox"/>	2. Send a Letter of Non-Repudiation to FDA. Click here for more info http://www.fda.gov/ForIndustry/ElectronicSubmissionsGateway/ucm113964.htm .
<input type="checkbox"/>	3. Obtain a personal digital certificate. Click here for more information on certificates http://www.accessdata.fda.gov/esg/userguide/webhelp/Digital_Certificates.htm .
<input type="checkbox"/>	4. Prepare a guidance compliant test submission. Each Center (CBER, CDER, etc.) has published guidance on the preparation of electronic submissions. Refer to the specific center web site for information about guidance compliant submissions (http://www.fda.gov/ForIndustry/ElectronicSubmissionsGateway/ucm113200.htm). If using FDA eSubmitter for the Center for Tobacco Products, you are not required to send a guidance compliant test submission.
<input type="checkbox"/>	5. Read the User Guide (http://www.accessdata.fda.gov/esg/userguide/webhelp/default.htm) and tutorials (http://www.fda.gov/ForIndustry/ElectronicSubmissionsGateway/ucm165609.htm) on the FDA ESG web site (http://www.fda.gov/esg). Review System Requirements (http://www.fda.gov/ForIndustry/ElectronicSubmissionsGateway/ucm110470.htm). Note: only Internet Explorer 6, 7, 8 and Firefox 2.0.x are compatible with ESG.
Request and Set Up Your Test Account (for assistance contact esgreg@gnsi.com)	
<i>Wait for email with information on how to register online for a WebTrader test account. (reply to email from Step 1)</i>	
<input type="checkbox"/>	6. Register for a WebTrader test account. Follow the steps outlined in the email and refer to "Registering for a web based test account" tutorial (http://www.fda.gov/ForIndustry/ElectronicSubmissionsGateway/ucm165609.htm) for detailed registration steps. You will need the public key for your personal digital certificate to complete this step. Note: The Primary Contact must be a real person; the "Company Name" is actually an account name and must be unique throughout the entire ESG test system. We recommend appending the user's initials to your company name.
<i>Wait for the WebTrader test account activation email. Account activation may take up to 48 hours.</i>	

	7. Activation email received. Follow the instructions to:
<input type="checkbox"/>	a. Install JRE (activation email will contain the specific version details)
<input type="checkbox"/>	b. Install JCE (activation email will contain the specific version details)
<input type="checkbox"/>	c. Configure your firewall (activation email will contain the details)
<input type="checkbox"/>	8. Prepare a load test submission. This submission need not be guidance compliant (the submission will not be reviewed by FDA), but should be representative of the file types you will be submitting in a typical submission (i.e., a mixture of PDF, text files, MS Word files, etc). The load test requirements for each Center are: <ul style="list-style-type: none"> a. 7.5 GB submission for CBER or CDER b. 2 GB submission for Center for Tobacco Products (load test is recommended if you expect your submission to exceed 2 GB) c. 1 GB submission for CDRH d. A load test is NOT required for CVM or OC (SPL submission)

Send Test Submissions

Log in to your ESG WebTrader test account (same URL to Register for a test account) with the user ID and password you created when you registered for your test account (step 7 above).

<input type="checkbox"/>	9. Send a small (20KB) text (.txt) file to the "Testing (GWTEST)" center with submission type "Connectivity Test". Refer to "sending a test submission" tutorial (http://www.fda.gov/ForIndustry/ElectronicSubmissionsGateway/ucm165609.htm) for detailed steps. Center for Tobacco Products submitters should send this test to "Center for Tobacco Products" center with submission type "Electronic Submission".
<input type="checkbox"/>	10. Send a guidance compliant test submission to the appropriate center (CBER, CDER, etc.) with appropriate submission type. See Item 4 above for more information. If using FDA eSubmitter for the Center for Tobacco Products, you are not required to send a guidance compliant test submission.
<input type="checkbox"/>	11. Send a load test to "Testing (GWTEST)" center and submission type "Size Test". See Item 4 above for more information.

The FDA will review your guidance complaint test submission, which may take up to 2 weeks. You will be notified by the ESG staff by email regarding submission status.

Set Up a Production Account

<input type="checkbox"/>	12. Once you have sent all test submissions and the guidance compliant submission meets FDA requirements, you will be sent an email with information on how to register for a production account.
<input type="checkbox"/>	13. Register for production WebTrader account following the steps outlined in the email. You will need the public key for your personal digital certificate to complete this step.

Wait for the WebTrader production account activation email. Account activation may take up to 48 hours.

<input type="checkbox"/>	14. Activation email received for the Production Account. Follow the instructions in the activation email.
	a. You must use the same computer that you used for testing.
	b. Make sure you have the JRE and JCE installed.

	c. Configure your firewall (activation email will contain the details)
Log in to your ESG WebTrader production account (same URL to register for a production account) with the user ID and password you created when you registered for a production account (step 13 above).	
<i>You are now ready to send electronic submissions to FDA using the ESG system.</i>	

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